

510(k) Summary

SEP 28 2012

Submitter: Bausch & Lomb, Inc.
30 Enterprise, Suite 450
Aliso Viejo, CA 92656

Contact Person: Jason Smith
Global Regulatory Affairs Manager
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Date Prepared: September 27, 2012

Trade name: Bausch + Lomb IOL Injector, INJ100

Classification Name: Intraocular lens guide (21 CFR 886.4300)

Predicate Devices:

1. K092023 Mediceal Naviject Sub2-1P IOL Injector Set
2. K063155 Alcon Monarch III IOL Delivery System

Device Description: The Bausch + Lomb IOL Injector is a sterile, single-use device used to fold and insert an intraocular lens through surgical procedure into a human eye. The system provides a tubular pathway through an incision over the iris, allowing delivery of an IOL into the capsular bag.

Indications for Use: The Bausch + Lomb IOL injector is indicated for folding and injection of Bausch + Lomb IOLs approved for use with this injector.

Comparative Analysis: The Bausch + Lomb IOL Injectors have been demonstrated to be equivalent to the predicate devices for their intended use.

Functional/Safety Testing: The Bausch + Lomb IOL Injectors have successfully undergone functional testing and are found to deliver the Bausch + Lomb IOLs in conformance with the requirements set forth in ISO 11979-3, section 5..

Conclusion: The Bausch + Lomb IOL Injectors are substantially equivalent to the predicate devices.

Comparison of Predicate Devices to the Proposed Bausch + Lomb IOL Injector

Characteristic	Predicate K092023 Medicel Naviject Sub2- 1P IOL Injector Set	Predicate K063155 Alcon Monarch III IOL Delivery System	Bausch + Lomb IOL Injector (Proposed Device)
Indications for use	Insertion only of models of intraocular lens that allow use of this injector in their labeling	Implantation of Alcon qualified Acrysof intraocular lenses into the eye following cataract removal	The Bausch + Lomb IOL injector is indicated for folding and injection of Bausch + Lomb IOLs approved for use with this injector.
Contraindications	The use of this injector system with other intraocular implants or cartridges, that have not been tested or approved for use by STAAR Surgical Company.	None	None
Injector configuration	User has to assemble three items: 1. Injector with plunger 2. Cartridge/tip assembly 3. Loader	User has to assemble two items: 1. Cartridge 2. Handpiece	No user assembly – the cartridge, tip, and injector are all one unit
Single use?	All three pieces are single-use only.	The cartridge is single use, the handpiece is reusable.	Single use
Sterile?	Sterile	Sterile	Sterile
How sterilized	Ethylene oxide	Ethylene oxide (cartridge) Steam (handpiece)	Ethylene oxide
Coating?	No	Hydrophilic coating	Hydrophilic coating
How sold?	Packs of ten	Cartridges are sold in packs of ten	Packs of ten



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

SEP 28 2012

Bausch & Lomb, Inc.
c/o Mr. Jason Smith
Global Regulatory Affairs Manager
30 Enterprise, Suite 450
Aliso Viego, CA 92656

Re: K113852

Trade/Device Name: Bausch + Lomb IOL Injector, INJ100
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I, Reserved
Product Code: MSS
Dated: September 13, 2012
Received: September 14, 2012

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

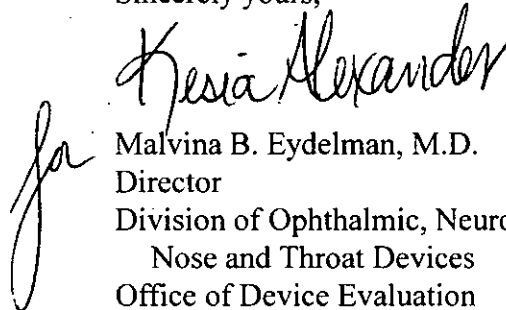
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Malvina B. Eydelman". To the left of the signature is a large, stylized handwritten letter "J" or "for".

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: Bausch + Lomb IOL Injector

Indications for Use:

The Bausch + Lomb IOL Injector is indicated for folding and injection of Bausch + Lomb IOLs approved for use with this injector.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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